UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION



| | | |
|---|---|---|
| CRISTY ESNARD AND STEPHEN ESNARD, Individually, and on Behalf of MEGHAN ESNARD, a minor child | § | |
| Plaintiffs, | § | CIVIL ACTION No. |
| v. | § | A03CA 201SS |
| MCNEIL CONSUMER & SPECIALTY PHARMACEUTICALS, a Division of MCNEIL-PPC, INC.; and JOHNSON & JOHNSON, | § | |
| Defendants. | § | |

**PLAINTIFFS' ORIGINAL COMPLAINT-DEMAND FOR JURY TRIAL**

COME NOW Cristy Esnard and Stephen Esnard, Individually, and on Behalf of Meghan Esnard, a minor child, (hereinafter "plaintiffs"), and file Plaintiffs' Original Complaint against McNeil Consumer & Specialty Pharmaceuticals, a Division of McNeil-PPC, Inc., and Johnson & Johnson, (hereinafter "defendants"), and would show the following:

## I.
## PARTIES

Plaintiffs Cristy Esnard and Stephen Esnard, Individually, and on Behalf of Meghan Esnard, a minor child, are citizens and residents of Harris County, Houston, Texas.

Defendant McNeil Consumer & Specialty Pharmaceuticals, a Division of McNeil-PPC, Inc., is a corporation organized under and by virtue of the laws of the state of New Jersey, with a principal place of business in Montgomery County, Pennsylvania. Service of process may be obtained on them by serving their registered agent for service, CT Corp. System, 350 N. St. Paul

Street, Dallas, Texas 75201.

Defendant Johnson & Johnson is a corporation organized under and by virtue of the laws of the state of New Jersey, with a principal place of business in Middlesex County, New Jersey. Service of process may be obtained on them by serving their registered agent for service, M. H. Ullmann, One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933-0000.

## II.
## JURISDICTION AND VENUE

Jurisdiction and venue are proper in the United States District Court, Western District of Texas, Austin Division, under 28 U.S.C. §1332, based on diversity of citizenship and the amount in controversy exceeding $75,000, because plaintiffs are citizens and residents of the State of Texas, and defendants are all corporations which are residents of states other than Texas; and under 28 U.S.C. §1391, because defendant McNeil owns and operates a major manufacturing plant in Round Rock, Williamson County, Texas, where the drug in question was manufactured, and because a substantial part of the events or omissions giving rise to this claim occurred in Williamson County, Texas.

Specifically, defendant McNeil Consumer & Specialty Pharmaceuticals, a Division of McNeil-PPC, Inc., (hereinafter "McNeil", or "the defendant McNeil") is a corporation organized under and by virtue of the laws of the state of New Jersey, and has a principal place of business in Montgomery County, Pennsylvania, which is qualified to do business in Texas, and doing business in Round Rock, Williamson County, Texas. Texas courts have personal jurisdiction over McNeil because it operates a major manufacturing facility in Williamson County, Texas, located within this District and Division, and conducts business throughout Texas, including this District and Division.

Defendant Johnson & Johnson (hereinafter "J & J", or "the defendant J & J") is a corporation organized under and by virtue of the laws of the state of New Jersey, and has a principal place of business in Middlesex County, New Jersey, which is qualified to do business in Texas, and also doing business in Arlington, Tarrant County, Texas, and through its wholly owned subsidiary, the defendant McNeil, in Williamson County, Texas. Thus, there is both subject matter and personal jurisdiction over both defendants in the Western District of Texas, Austin Division.

## III.
## STATEMENT OF FACTS

Defendant McNeil is a wholly owned subsidiary of defendant J & J, and both were at all material times hereto in the business of designing, manufacturing and marketing an over-the-counter (OTC) nonsteroidal anti-inflammatory analgesic drug called Children's Motrin, generic name ibuprofen (hereinafter "the drug"). Defendant McNeil is primarily responsible for manufacturing and distributing the drug, under the direction and control of defendant J & J, and a substantial amount of the research, design, manufacturing, marketing and distribution activities regarding the drug take place at the Round Rock, Williamson County, Texas, plant.

McNeil is in the business of designing, manufacturing, selling and distributing the drug OTC directly to consumers and users in Texas and throughout the United States through various retailers, including but not limited to grocery stores and pharmacies. Defendants intended that the product reach the user or consumer such as plaintiffs in the condition in which it was originally sold and distributed by them.

Further, defendants put this product into the stream of commerce without any alteration or modification of the product by any distributor or retailer. Additionally, at all material times

defendants manufactured, distributed, and marketed the drug to be sold to consumers in Texas and throughout the Unites States.

On or about June 7, 2002, Meghan Esnard, an almost five year-old female with no known drug allergies, was in a state of good health when she was given the Motrin for fever and sore throat by her parents, Cristy and Stephen Esnard. On or about June10, 2002, she broke out in a rash that started behind her ears, face, and knees. It was erythematous, small papules rough rash that itches. The rash then spread to her chest, abdomen, back and to the extremities, and then it gradually spread downward.

Then, on or about June 17, 2002, Meghan was admitted to Memorial Hermann Children's Hospital in Houston, Texas where she was diagnosed with Stevens-Johnson Syndrome ("SJS"). During her hospitalization, she was in excruciating pain caused by her skin desquamation, comparable to second degree burns. She was then discharged on June 20, 2002. On or about June 22, 2002, Meghan had facial swelling and increased itching. She was seen in the ER early on June 23, 2002. She was discharged home, but early the next morning she had severely increased facial swelling, fever and itching.

She went back to Memorial Hermann Hospital and was admitted on June 24, 2002. An allergy and immunology consultation suggested a drug reaction to the Motrin, which caused a systemic reaction, including in the kidneys, to eventually cause interstitial nephritis, thereby causing proteinuria, hematuria, and edema of the face and abdomen. She will require permanent medical and custodial care for her catastrophic injuries, as well as require future medical testing on her kidneys and other organs.

Plaintiffs had no knowledge of any unseen potential dangerous defect or condition in the

drug at the time Meghan used it, and certainly no knowledge that it could cause SJS or Toxic Epidermal Necrolysis ("TEN"), or kidney damage.

Nor did McNeil or J & J warn in any of the materials distributed with the drug to the consumer, either in the box label or the bottle label, or in any of its advertising designed to reach the consumer, that the drug could cause SJS/TEN, or a mucocutaneous lesion, or kidney damage, or what to do if a rash or mucosal lesions developed. Plaintiffs used the drug in the manner intended and in accordance with instructions included with the drug by defendants for use as pharmacologic treatment for fever. As a direct and proximate result of using the drug, plaintiff Meghan Esnard suffered serious, painful, and permanently disabling injuries, and her parents suffered impairment to the parent-child relationship and medical expenses.

## IV.
## CAUSE OF ACTION AGAINST ALL DEFENDANTS

### A. Defective Design

Plaintiffs adopt all of the foregoing allegations in paragraphs III by reference, as if incorporated verbatim herein. Additionally, they allege that the drug was defectively designed by defendants McNeil and J & J so as to render it unreasonably dangerous to plaintiff and other persons similarly situated. In particular, it contained the chemical constituent propionic acid and other ingredients, rendering it more toxic than other non-propionic acid based NSAID drugs, and more dangerous to certain persons, particularly females and children, than other NSAIDS or fever-reducing products.

Additionally, defendants failed to adequately test the drug for over the counter use with children before presenting it to the FDA for such use, and before selling and distributing it to the general public; and/or failed to adequately and completely report the clinical trials data regarding

the drug. Specifically, they eliminated severely dehydrated children from their studies, thereby skewing the results to show no significant kidney damage to children in the study.

Additionally, a safer alternative design would have prevented or significantly reduced the risk of plaintiff's injuries, without substantially impairing the drug's utility. Furthermore, a safer alternative design was economically and technologically feasible at the time the drug left the control of defendants by the application of existing or reasonably achievable scientific knowledge. Finally, the drug's risk to children far outweighed its benefit, particularly considering that there were other drugs on the market, such as Tylenol, which were safer and equally as effective.

**B. Marketing Defect**

Plaintiffs adopt all of the foregoing allegations in paragraphs III and IV by reference, as if incorporated verbatim herein. Additionally, they allege that the drug was also defective and unreasonably dangerous because there was no warning, or alternatively, no adequate warning that consumption of this drug could result in SJS or TEN, or in any type of severe life-threatening skin reaction; or that it could cause kidney toxicity, particularly in severely dehydrated children like Meghan Esnard.

The warnings and instructions that accompanied the drug provided inadequate warnings to the consumer about the risk of SJS/TEN, the degree of the risk of SJS/TEN, and about other serious skin reactions or kidney problems associated with the use of the drug, or what to do in the event the patient suffered an adverse skin reaction to the drug. Specifically, the warning was inadequate in the following respects:

1. There was no warning that if a rash or mucosal reaction developed, that the drug

should be stopped immediately and medical care should be sought.

2. Nor was there any warning that there was a greater risk of such skin reactions in females.

3. Nor was there any warning that the drug could cause renal or kidney damage in severely dehydrated children such as Meghan Esnard.

4. Nor was there any warning that if a worsening of symptoms associated with a virus or an infection or signs of a new infection developed, that the parents should stop the drug immediately and call the doctor.

These marketing defects were the producing cause of the plaintiff's permanent injuries and damages.

**C. Breach of Express Warranty**

Plaintiffs adopt all of the foregoing allegations in paragraphs III and IV by reference, as if incorporated verbatim herein. Additionally, they allege that defendants made express warranties as to the drug's utility in treating fever and pain symptoms/conditions, without making clear the extreme danger associated with a toxic reaction to this drug. The express warranties described were part of the basis of the bargain between plaintiffs and defendants. The drug was not of the quality or condition expressly warranted by the defendants' affirmations, and defective in that the drug is inherently dangerous to children, particularly females, and therefore cannot be used in the manner intended without serious risk of physical injury to the user.

**D. Breach of Implied Warranty**

Plaintiffs adopt all of the foregoing allegations in paragraphs III and IV by reference as if incorporated verbatim herein. In addition, they allege that defendants impliedly warranted to the public generally and specifically to the plaintiffs that the drug was of merchantable quality and was safe and fit for the purpose intended when used under ordinary circumstances and in an

ordinary manner. Defendants knew or had reason to know of the purposes for which plaintiffs purchased the drug; that plaintiffs were relying on defendants' skill and judgment to select and furnish a suitable drug; and that the drug in question were unfit for the purpose for which it was intended to be used.

**E. Negligence**

Plaintiffs adopt all of the foregoing allegations in paragraphs III and IV by reference as if incorporated verbatim herein. Additionally, they allege that defendants, particularly the defendant McNeil, had a duty to use reasonable care in labeling, packaging, marketing, selling, advertising, warning, and otherwise distributing the drug. However, McNeil placed the drug on the market without warning the user or consumer that consumption of this drug could result in SJS or TEN, or other severe skin reactions.

Additionally, they failed to warn plaintiffs to stop the drug immediately and seek medical attention if any skin rash or mucosal lesions developed, because of the danger that such symptoms could progress to SJS/TEN. These acts and omissions, taken by themselves or in combination, were negligence and were a proximate cause of the plaintiff's permanent injuries and damages.

**F. Deceptive Trade Act Violations**

Plaintiffs adopt all of the foregoing allegations in paragraphs III and IV by reference as if incorporated verbatim herein. Additionally, plaintiffs finally allege a violation of the Texas Deceptive Trade Practices Act ("DTPA"), Bus. & Commerce Code Sections 17.46(b) & 17.50, in that defendants used false and misleading statements in the drug literature distributed regarding the drug; and alternatively, breached express and/or implied warranties under the Act, resulting

in economic damages and mental anguish. Additionally, plaintiffs allege that they are entitled to treble damages because defendants intentionally diluted the warnings they gave regarding this potentially disastrous toxic reaction.

Each and all of the foregoing acts or omissions on the part of defendants, acting separately and collectively, were a proximate cause of the injuries and damages sustained by the plaintiffs herein.

## V.
## DAMAGES

Plaintiffs seek damages from defendants, jointly and severally, for the injuries and damages caused by use of the product manufactured, marketed and sold by defendants in an amount in excess of the minimum jurisdictional limits of this Court. It is not possible for plaintiffs to plead the exact amount of these damages at this time, but they will be pleaded at a later time when they can be determined and as may be required by the rules.

Plaintiffs allege that the foregoing negligence and strict liability of defendants, acting separately and collectively, was a direct, proximate and/or producing cause of the damages suffered by plaintiffs herein.

As a direct and proximate/producing result of the negligence and strict liability of defendants as set out above, Plaintiff Meghan Esnard has suffered the following injuries and damages, among others, for which defendants are jointly and severally liable:

1. Plaintiff Meghan Esnard has suffered physical impairment in the past and, in reasonable probability, such impairment will continue into the future;

2. Plaintiff Meghan Esnard has incurred extensive past medical and rehabilitation expenses for treatment of her injuries, and will incur future reasonable and necessary expenses for such medical care and treatment;

3. Plaintiff Meghan Esnard has suffered severe physical pain and mental anguish caused by her injuries, treatment and rehabilitation, and, in all reasonable probability, will continue to suffer in this matter in the future;

4. Plaintiff Meghan Esnard has suffered physical disability, and disfigurement in the past, and will continue to suffer from this disability and disfigurement in the future;

As a direct and proximate result of the negligence and strict liability of defendants as set out above, Plaintiffs Cristy Esnard and Stephen Esnard have suffered the following injuries and damages, among others, for which defendants are jointly and severally liable:

1. Past and future loss of consortium, companionship, and impairment to the parent-child relationship;

2. Medical, rehabilitative, and attendant care expenses to age 18 for Meghan.

Plaintiffs request and hereby claim prejudgment and post-judgment interest as provided by law.

## VI.
## PUNITIVE AND TREBLE DAMAGES

As a result of defendants' negligence and gross negligence in designing, manufacturing and placing into the stream of commerce a drug unsafe for the purpose intended; in failing to adequately warn the ultimate user and consumer of the inherent dangers in said drug; in failing to provide instructions for the safe use of said dangerous drug when defendants knew or should have known of the probable harm, injury or death the drug could cause to the user; and in deliberately failing to warn about the danger of the potentially disastrous toxic of SJS/TEN and renal damage; defendants should be held liable for gross negligence and intentional misconduct. Plaintiffs are therefore entitled to punitive and exemplary damages for the gross negligence of defendants. Plaintiffs also allege that each act of negligence by all of the defendants constituted

individual and/or collective acts of gross negligence and/or malice against plaintiffs.

Specifically, plaintiffs adopt each of the allegations in paragraph III and IV by reference. These acts of negligence by all defendants involved an extreme degree of risk of harm to the plaintiffs. Specifically, there was a high degree of risk of harm from SJS/TEN from this drug due to its constituents. Yet, they proceeded with conscious indifference to Meghan Esnard's safety and welfare; and/or alternatively, showed such actual conscious indifference to the rights, welfare, and safety of plaintiff to constitute gross negligence. Additionally and finally, plaintiffs seek treble damages under the DTPA for violations of that Act.

## VII.
## JURY DEMAND

Plaintiffs respectfully request a trial by jury and are tendering the required jury fee with this complaint.

WHEREFORE, PREMISES CONSIDERED, plaintiffs pray that defendants be cited to appear and answer herein, that upon final hearing of this cause, plaintiffs have judgment against defendants for actual, punitive, and treble damages as provided by law, together with interest as provided by law and costs of court, attorney's fees, and for such other and further relief, general and special, to which plaintiffs may be entitled, either at law or in equity.

Dated this 1st day of April, 2003.

Respectfully submitted,

**LAW OFFICES OF JAMES C. BARBER**
4310 Gaston Avenue
Dallas, Texas 75246
Phone: (214) 821-8840
Fax: (214) 821-3834

By: _____

**JAMES C. BARBER**
State Bar No. 01706000
**JASON S. MARINA**
State Bar No. 24011738

**ATTORNEYS FOR PLAINTIFFS**